IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8635

Bartle, C.J. April 18, 2011

Nancy L. O'Dell ("Ms. O'Dell" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In May, 2004, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Georgina Sehapayak, M.D., F.A.C.S., F.A.S.R.S. Based on an echocardiogram dated February 15, 2002, Dr. Sehapayak attested in Part II of Ms. O'Dell's Green Form that she suffered from moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left atrial dimension, and arrhythmias.[3] Based on such findings, claimant would be

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2. (...continued)
not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Dr. Sehapayak also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

entitled to Matrix A-1, Level II benefits in the amount of $424,211.[4]

In the report of claimant's echocardiogram, Dr. Sehapayak stated that, "Doppler study shows mild-to-moderate [mitral regurgitation]." Dr. Sehapayak did not specify a percentage as to the level of claimant's mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA"), in any apical view, is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In September, 2006, the Trust forwarded the claim for review by Zuyue Wang, M.D., one of its auditing cardiologists. In audit, Dr. Wang concluded that there was no reasonable medical basis for Dr. Sehapayak's finding that claimant had moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation. Dr. Wang stated that "[t]he RJA/LAA ratio is less than 20%. The RJA encircled should not include the area of low velocity flow."

Based on Dr. Wang's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. O'Dell's claim. Pursuant to the Rules for the Audit

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4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b).

of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[5] In contest, claimant argued that, prior to taking Diet Drugs, she had no pre-existing medical conditions. In addition, claimant asserted that she should prevail on her claim because the attesting physician's finding of moderate mitral regurgitation was supported by an additional echocardiogram report for a January 8, 2001 echocardiogram, prepared by Soe-Ni Nick Kong, M.D., which stated that claimant had "[m]oderate mitral regurgitation."[6] Claimant also stated that there is a reasonable medical basis for her claim because her attesting physician "was working for the A.H.P. Settlement Trust," and that a letter from the Trust regarding her echocardiogram performed in the Screening Program[7] confirmed that she had moderate mitral regurgitation. Finally, claimant argued that the fact that her "left atrium is significantly dilated ... is a sign that regurgitation is probably moderate because mild mitral regurgitation would not lead to a dilated left atrium."

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5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. O'Dell's claim.

6. Dr. Kong did not specify a percentage as to the level of claimant's mitral regurgitation.

7. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

The Trust then issued a final post-audit determination again denying Ms. O'Dell's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. O'Dell's claim should be paid. On June 12, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7252 (June 12, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 5, 2007. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[8] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare

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8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for a finding that the claimant had moderate mitral regurgitation, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. O'Dell reasserts the arguments that she made in contest; namely, that because the auditing cardiologist agreed that claimant had an abnormal left atrial dimension, there is a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation.

In response, the Trust argues that claimant failed to establish a reasonable medical basis for her claim because she did not rebut Dr. Wang's specific determination in audit that claimant's attesting physician improperly characterized low velocity flow as mitral regurgitation. The Trust also asserts

that the presence of an abnormal left atrial dimension does not establish a reasonable medical basis for Dr. Sehapayak's finding of moderate mitral regurgitation.

The Technical Advisor, Dr. Vigilante, reviewed claimant's February 15, 2002 and January 8, 2001 echocardiograms and concluded that, although the February 15, 2002 echocardiogram demonstrates only mild mitral regurgitation, there is a reasonable medical basis for finding that the echocardiogram of January 8, 2001 demonstrates moderate mitral regurgitation. Specifically, Dr. Vigilante stated in reference to the January 8, 2001 echocardiogram that:

> Visually, moderate mitral regurgitation was noted on this study. This mitral regurgitant jet was a posteriorly directed jet noted in the parasternal and apical views. I digitized those cardiac cycles in the apical four and two chamber views in which the mitral regurgitant jet was best evaluated. I then digitally traced and calculated the RJA and LAA. I determined that the largest representative RJA was 5.0 cm2 in the apical four chamber view. This measurement occurred with appropriate Doppler gain and at a Nyquist limit of 58 cm per second at a depth of 18 cm. There was no sonographer RJA measurement on this study. I determined that the LAA was 23.1 cm2 in the apical four chamber view. This result correlates well with the sonographer's LAA measurement of 22.9 cm2. Therefore, the largest representative RJA/LAA ratio in the apical four chamber view was 22%. This ratio qualifies for moderate mitral regurgitation. In the apical two chamber view, I determined that the largest representative RJA was 5.5 cm2. I calculated the LAA to be 22.8 cm2 in the apical two chamber view. Therefore, the largest representative RJA/LAA ratio in the apical two chamber view was 24%. This

> ratio qualifies for moderate mitral regurgitation.

Dr. Vigilante further noted that the January 8, 2001 echocardiogram demonstrated an abnormal left atrial dimension. He explained:

> Visually, the left atrium appeared enlarged. I digitized the cardiac cycles in the parasternal long-axis and apical four chamber views in which the left atrium appeared the largest. I measured the left atrium by electronic calipers. I determined that the left atrial antero-posterior diameter was 4.7 cm. This measurement was taken between the posterior root of the aorta and posterior left atrial wall at the level of the aortic valve. This line was perpendicular to the supero-inferior axis of the left atrium. I determined that the left atrium measured 6.0 cm in the supero-inferior dimension. This measurement was taken from the mitral annulus to the posterior left atrial wall. This measurement was perpendicular to the mitral annulus. I excluded pulmonary vein structures in this measurement.

Finally, Dr. Vigilante determined that "[t]here was obvious calcification of the postero-lateral region of the mitral annulus seen in the apical four and two chamber views. This mitral annular calcification was represented by increased echoes and increased reflectance of these echoes in the annulus."[9]

In response to the Technical Advisor Report, claimant argues that she is entitled to Level II Matrix Benefits because Dr. Vigilante confirmed that her January 8, 2001 echocardiogram demonstrated moderate mitral regurgitation and an abnormal left

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9. Under the Settlement Agreement, the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d).

atrial dimension. Ms. O'Dell, however, concedes that her claim is payable on Matrix B-1.

After reviewing the entire Show Cause Record, we find that claimant has established a reasonable medical basis for Level II Matrix Benefits. In the report of claimant's echocardiogram dated January 8, 2001, Dr. Kong concluded that Ms. O'Dell had "[m]oderate mitral regurgitation" and "[b]iatrial enlargement." Dr. Vigilante reviewed claimant's January 8, 2001 echocardiogram and determined that Ms. O'Dell suffered from moderate mitral regurgitation and an abnormal left atrial dimension.[10]

Specifically, Dr. Vigilante measured RJA/LAA ratios of 22% and 24% and concluded that "the RJA/LAA ratio is greater than 20% in several cardiac cycles in the apical two and four chamber views." As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See id. § I.22.

Dr. Vigilante also concluded that claimant's "left atrial antero-posterior diameter was 4.7 cm" and that her "left atrium measured 6.0 cm in the supero-inferior dimension." The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the

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10. Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.

parasternal long-axis view. See id § IV.B.2.c.(2)(b)ii). Under these particular circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim for Level II Matrix Benefits.

For the foregoing reasons, we conclude that claimant has met her burden of proving that there is a reasonable medical basis for her claim and that she consequently is entitled to Matrix B-1, Level II benefits. Therefore, we will reverse the Trust's denial of Ms. O'Dell's claim for Matrix Benefits.